IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF PUERTO RICO

UNITED STATES OF AMERICA

Plaintiff

v.

8,280 / 10-ounce bottles, more or less, of an article of drug, labeled in part: "***Bee-Shield*** Hand Sanitizer INSTANT SANITIZING GEL *** Kills 99.99% of Virus, Bacterias and Fungies*** 10oz.***";

475 / 1-gallon containers, more or less, of an article of drug, labeled in part: "***Bee-Shield*** Hand Sanitizer INSTANT SANITIZING GEL *** Kills 99.99% of Virus, Bacterias and Fungies*** 1 Gal.***;

73 / 5-gallon pails, more or less, of an article of drug purporting to be Bee-Shield Hand Sanitizer;

14 / 275-gallon plastic/metal tubs, more or less, of an article of drug purporting to be Bee-Shield Hand Sanitizer,

Defendants

CIVIL NO. 10-1530 (SEC)

AMENDED VERIFIED COMPLAINT FOR FORFEITURE

TO THE HONORABLE COURT:

COMES NOW the United States of America represented by its undersigned attorneys and very respectfully allege and pray:

NATURE OF THE ACTION

1. That this complaint is filed by the United States of America, and requests seizure and condemnation of articles of drug, as described in the caption, in accordance with the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*

2. That there is at Humacao, Puerto Rico, in the possession of Lord Pharmaceutical, LLC., d/b/a Bee International Distributors and/or Mr. Edgardo Paris, Road #938, Km 1.3, Sector Mambiche Prieto, and at Maunabo, Puerto Rico, in the possession of Puerto Rico Beverage, Inc., Road #3 Km 106.9, Urb. Industrial Urbana, or elsewhere within the jurisdiction of this Court, an article of drug, as described in the caption, which article consist in whole or in part of components that were shipped in interstate commerce from outside the Commonwealth of Puerto Rico. The approximate quantities and descriptions of the article at each site are as follow:

a. Humacao, Puerto Rico: 1) Fourteen (14) two hundred and seventy five (275) gallon plastic/metal tub containers of Bee Shield Hand Sanitizer; 2) fifty-nine (59) one (1) gallon containers of Bee Shield Hand Sanitizer; and 3) six thousand nine hundred sixty (6,960) ten-ounce (10 oz.) bottles of Bee Shield Hand Sanitizer.

b. Maunabo, Puerto Rico: 1) Seventy three (73) five (5) gallon pails of Bee Shield Hand Sanitizer; 2) four hundred sixteen (416) one (1) gallon containers of Bee Shield Hand Sanitizer; and 3) one thousand three hundred twenty (1,320) ten-ounce (10 oz.) bottles of Bee Shield Hand Sanitizer.

JURISDICTION AND VENUE

3. The United States of America brings this action *in rem* to condemn and forfeit the defendant property. This Court has jurisdiction over an action commenced by the United States under 28 U.S.C. § 1345 and 21 U.S.C. § 334, which provides the court with jurisdiction over seizures

brought under the Act.

4. That this Court has *in rem* jurisdiction over the defendant property because the defendant is located in the District of Puerto Rico. Upon filing of this complaint, the Plaintiff requests the Court issue an arrest warrant *in rem* pursuant to Supplemental Rule G(3)(b), which the Plaintiff will execute upon the property pursuant to Supplemental Rule G(3).

5. That venue is proper in this district pursuant to 28 U.S.C. § 1395(b) and 21 U.S.C. § 334(a)(1) because the defendant property is located in the District of Puerto Rico at Humacao, Puerto Rico, in the possession of Lord Pharmaceutical, LLC., d/b/a Bee International Distributors Road #938, Km 1.3, Sector Mambiche Prieto, and at Maunabo, Puerto Rico, in the possession of Puerto Rico Beverage, Inc., Road #3 Km 106.9, Urb. Industrial Urbana.

BASIS FOR FORFEITURE

6. The article described in the above caption is a new drug, as defined by Section 201(p) of the Act, (21 U.S.C. § 321(p)), because it is not generally recognized as safe and effective for its labeled uses. Specifically, the article is subject to the final monograph for Topical Antifungal Drug Products at 21 C.F.R. Part 333 Subpart C, because its labeling contains antifungal treatment claims. However, the final monograph for OTC Topical Antifungal Drug Products, does not include use as a hand sanitizer, which has been included in its label, causing the article to be an unapproved new drug for this indication. 21 C.F.R. 333.250(b).

Moreover, the active ingredient of Benzalkonium Chloride NF 0.13% is not a generally recognized safe and effective over-the-counter (OTC) antifungal active ingredient, 21 C.F.R. § 333.210 (2010). As a result, the article, as formulated and labeled, does not conform to the final monograph for OTC Topical Antifungal Drug Products at 21 C.F.R. Part 333 Subpart C. Additionally, the article's representation that it prevents the disease caused by H1N1 and

effectiveness against viruses, and claim for extended antimicrobial efficacy, are not covered under the OTC Drug Review.

The article is a drug that may not be introduced or delivered for introduction into interstate commerce pursuant to 21 U.S.C. § 355(a) in that it is a new drug within the meaning of 21 U.S.C. § 321(p) and no approval of an application filed pursuant to 21 U.S.C. § 355(b) is in effect for such drug.

7. That the articles are adulterated while held for sale after shipment of one or more of its components in interstate commerce, within the meaning of the Act, 21 U.S.C. § 351(a)(2)(B), in that the methods used in, and the facilities and controls used for, its manufacture, processing, packing, and holding do not conform to and are not operated and administered in conformity with current good manufacturing practice (GMP) requirements for drugs. 21 C.F.R. Part 211. Thus, there is no assurance that the drug meets the safety requirements of the Act, and has the identity and strength, and meets the quality and purity characteristics, which it purports and is represented to possess.

8. That the articles are misbranded while held for sale after shipment of one or more of its components in interstate commerce, within the meaning of the Act, 21 U.S.C. § 352, as follows:

- 352(b) in that it is in package form and its label fails to contain the place of business of the manufacturer, packer, or distributor;
- 352(e)(l)(A)(iii) in that its label fails to bear the established name of each inactive ingredient listed in alphabetical order; and, the label fails to list propylene glycol as an inactive ingredient;
- 352(f)(1) in that its labeling fails to bear adequate directions for use because the directions for use on the label are not in accordance with the directions for antifungal OTC products set forth at 21 C.F.R. § 333.250(d); nor are they adequate directions

for virus-related and H1N1 indications for use; and it is not exempt under 21 C.F.R. § 201.115 from bearing adequate directions for use, since it is an unapproved new drug; and

- 352(o) in that it is a drug and it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under 21 U.S.C. 360, and not included in a list required by 21 U.S.C.360(j).

9. That by reason of the foregoing, the articles are held illegally within the jurisdiction of this Court and are liable to seizure and condemnation.

FACTS

10. Puerto Rico Beverage is a contract manufacturer that manufactured and packaged product for Lord Pharmaceutical, LLC., under the Bee-Shield label and for Morales Distributors under the MD Quality label for distribution in Puerto Rico.

11. An FDA inspection of Puerto Rico Beverage conducted between August 19 and September 28, 2009, revealed numerous significant GMP violations, including the following:

(a) Failure to have a Quality Control Unit with the responsibility and authority to approve or reject all components, drug product containers, closures, in process materials, packaging materials, labeling, and drug products, and the authority to review production records to assure that no errors have occurred (21 C.F.R. § 211.22(a));

(b) failure to maintain the buildings used in the manufacture, processing, packing or holding of drug products in a clean and sanitary condition (21 C.F.R. § 211.56(a));

(c) failure to have a stability testing program for the firm's finished drug products, and the absence of the required stability data to support expiration dating for products

(21 C.F.R. § 211.137(a));

(d) failure to conduct determinations of conformance to appropriate written specifications for acceptance prior to the release of drug products (21 C.F.R. § 211.165(a));

(e) failure to conduct appropriate laboratory testing on each batch of drug product required to be free of objectionable microorganisms (21 C.F.R. § 211.165(b));

(f) failure to have a written testing program designed to assess the stability characteristics of drug products in order to determine appropriate storage conditions and expirations dates (21 C.F.R. § 211.166(a));

(g) failure to maintain master production and control records (21 C.F.R. § 211.186(a)); and

(h) failure to prepare batch production and control records that document the accomplishment of each significant step in the manufacture, processing, packing, or holding of the batch (21 C.F.R. § 211.188(b)).

12. Following the August-September 2009 inspection, Puerto Rico Beverage ceased manufacturing and Lord Pharmaceutical, LLC. committed to recalling and destroying all stocks of the article. However, the firm has continually delayed following through on their commitments and has not destroyed the article. Under these circumstances, seizure of the article is necessary.

WHEREFORE, the United States respectfully requests from this Honorable Court to issue a Warrant of Arrest *In Rem* against the article described in the caption of this case; that all persons having any interest in the article be cited to appear herein and answer the allegations of the complaint; that this Court decree the condemnation of the article and grant plaintiff the costs of this proceeding against the claimant of the article; that the article be disposed of as this Court may direct

pursuant to the provisions of the Act; and that plaintiff have such other and further relief as the case may require.

VERIFICATION

Carlos A. Medina declares and says that:

I, Carlos A. Medina, Compliance Officer, U.S. Food and Drug Administration, Department of Health and Human Services, have read the foregoing Complaint, and the statements contained therein are true to the best of my knowledge and belief. I declare under penalty of perjury that the foregoing is true and correct.

Executed in San Juan, Puerto Rico, this 21st day of June, 2010.

Carlos A. Medina
Compliance Officer
U.S. Food and Drug Administration

RESPECTFULLY SUBMITTED.

In San Juan, Puerto Rico, this 21st day of June, 2010.

Rosa E. Rodriguez-Velez
United States Attorney
District of Puerto Rico

s/ Hector E. Ramirez-Carbo
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